

REMARKS

This Amendment is filed in response to the Office Action mailed June 25, 2004, for which an unextended response is due September 25, 2004. Claims 1-17 are pending. New claims 18-30 are added for which support can be found, *inter alia*, throughout the specification, including within Examples 1-10. Claims 1 and 13 are presently amended. The allowance of claims 8-13 is noted with appreciation. Applicants respectfully request reconsideration of the rejection or objection of claims 1-7 and 14-17 in view of the foregoing remarks and amendments. No new matter has been added.

Claims 1 and 13 have been amended to more particularly point out and distinctly claim the present invention. More specifically, Claim 1 has been amended to recite that the transcriptional promoter to which the gene encoding at least one HSV protein, or truncated form thereof, is operably linked is selected from a group consisting of a cytomegalovirus promoter ("CMV"), a strong immunoglobulin promoter and a rous sarcoma virus ("RSV") promoter. Support for this amendment can be found throughout the specification, specifically on page 14, lines 14-18, and page 15, lines 5-9. Claim 13 has been amended to correct an editorial oversight. Support for the amendment to claim 13 can be found on page 19, lines 2-12, of the specification. No new matter is added by the amendments to claims 1 and 13.

Rejection of Claims 1-3, 15 and 17 Under 35 U.S.C. § 102(b)

Claims 1-3, 15 and 17 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Burke (1991, *Review of Infectious Diseases* 13 (Suppl. 11):S906-911). It is stated that the plasmid disclosed in Figure 1 of the cited reference "has all of the structural features recited in the claims." Applicants respectfully overcome the rejection in light of the following amendment to claim 1.

Claim 1 has been amended to recite that the transcriptional promoter to which the gene encoding at least one HSV protein or truncated form is operably linked is selected from a group consisting of a CMV promoter, a strong immunoglobulin promoter and a RSV promoter. Support for this amendment is found on page 14, lines 14-18, and page 15, lines 5-9, of the specification and additionally in the plasmid expression vectors exemplified in the Examples section of the instant application. Applicants assert that the amendment to claim 1 in this manner clearly differentiates the present invention from the cited prior art.

Applicants would further like to point out the differences between the subject matter of the rejected claims and the cited reference. Clearly absent from Burke is any discussion or suggestion

of the use of the plasmid vector diagrammed in Figure 1 as a polynucleotide vaccine to be introduced into vertebrate tissue for the purpose of inducing anti-HSV antibodies or a protective immune response against HSV. Instead, Burke demonstrates the use of recombinant DNA technology to produce viral glycoproteins for the generation of a subunit vaccine to HSV. Specifically, after stably transfecting a cell line with the plasmid diagrammed in Figure 1, the HSV glycoprotein encoded by the gene comprised within the plasmid was secreted into the growth medium and later purified. The purified HSV glycoprotein was used to immunize guinea pigs against HSV. Prior to this disclosed method, studies investigating the development of an effective HSV vaccine used a mixture of glycoproteins purified from cells infected with HSV to immunize animals against the virus. For use in an immunization regimen against HSV, Burke states that more defined viral glycoproteins are advantageous over glycoproteins purified from virus-infected cells. The article further investigates the role that vaccine delivery vehicles play in the immunogenicity of protein-based vaccines, finding this a critical factor when designing such vaccines. In comparison to the above, claim 1 of the instant application clearly states that the plasmid expression vector contemplated as part of the present invention is used for the *in vivo* induction of anti-HSV antibodies or protective immune responses when introduced into vertebrate tissue, not for the recombinant production of HSV glycoproteins in a eukaryotic cell line for later administration of protein to vertebrate subjects.

In light of the amendment to claim 1, Applicants respectfully request withdrawal of the rejection of claims 1-3, 15 and 17 under 35 U.S.C. § 102(b).

Claim Objections

Claims 4-7, 14 and 16 are objected to for depending upon a rejected base claim. Applicants assert that this objection is overcome with the previously discussed amendment to claim 1 to a form in condition for allowance. Therefore, it is respectfully requested that this objection be withdrawn.

In view of the amendments and comments herein, Applicants respectfully take the position that all claims are in proper form for allowance and earnestly solicit a favorable action on the merits. The Examiner is invited to contact the undersigned attorney if clarification is required on any aspect of this response, or if any of the claims are considered to require further amendment to be placed in condition for allowance after entry of this Amendment.

Respectfully submitted,

By Laura M. Ginkel

Laura M. Ginkel

Reg. No. 51,737

Attorney for Applicant

MERCK & CO., INC.

P.O. Box 2000

Rahway, New Jersey 07065-0907

(732) 594-1932

Date: Sept. 23, 2004